

REMARKS

Previously, Claims 3-21 and 86-109 were pending before the Examiner. In this paper, Applicant has amended Claims 7 and 10. Applicant has added new Claims 110-114. No Claims have been cancelled. Therefore, Claims 3-21 and 86-114 are pending. As discussed below, no new matter has been added with the amendments herein.

Personal Interview

Applicant thanks Examiner Koharski for the courteous and helpful personal interview with Applicant's attorney, Andrew Douglas, conducted on August 15, 2008. That interview is summarized above.

The Present Amendment is Responsive to the Outstanding Office Action

In the Office Action, the Examiner indicated that Applicant's response filed on March 11, 2008 is not fully responsive to the prior Office Action. In particular, the Examiner indicated that Applicant's amendment is drawn a non-elected embodiment. Applicant respectfully disagrees with the Examiner and, therefore, traverses the present objection. To expedite prosecution of this application, however, Applicant has amended the claims, drawings, and specification to further clarify the systems and devices of the present application.

Applicant has added herewith Figure 23E, which illustrates a multilumen cannula having a tip portion as illustrated in Figures 23A and 23B. New Figure 23E is fully supported by the application as originally filed, including at least Paragraphs [0096]-[0102], [0129], and [0168]-[0179], Figures 10 and 11, and Claims 9, 20, 40, 41, 48, 54, 61, 68, 77, and 83. For example, Paragraph [0102] explains that details of multilumen cannulae are described in connection with Figures 11 and 17A-24. In Paragraph [0129], which provides an overview for Figures 17A-24, Applicant explains that "application of a heart assist system to a patient can involve inserting a cannula into the patient's vasculature to deliver and/or withdraw blood" and such cannulae "may be single lumen, as shown in Figures 1-9 and 12-13, or multilumen, as shown in Figures 10-11." Moreover, at least ten claims as originally filed include recitations where a blood flow lumen comprises a first blood flow lumen and a second blood flow lumen.

Applicant has amended the specification to refer to Figure 23E. Applicant has also amended Claims 7 and 10 to further define the cannula and pumping system, respectively, of those claims. Such amendments are fully supported by the application as originally filed for at least the reasons provided above. Thus, Applicant has not added any new matter.

Applicant notes that in the cannula and pumping systems of Claims 7 and 10, blood can enter an inlet in a cannula. For example, blood can enter an inlet adjacent the proximal end of the cannula or blood can enter a lumen at an inlet as shown in Figure 23E.

Accordingly, Applicant respectfully requests that the Examiner withdraw the holding of non-responsiveness and examine on the merits the claims set forth herein.

The Pending Claims Are in Condition for Allowance

For at least the reasons provided in Applicant's amendment dated March 11, 2008, the pending claims are in condition for immediate allowance. In addition, the pending claims are in condition for allowance for the additional reasons provided herein.

Applicant would like to direct the Examiner's attention to Applicant's remarks in its Amendment dated March 11, 2008, specifically pages 9-13. Those pages outline the outstanding objections and rejections, and provide a discussion of U.S. Patent No. 3,995,617 to Watkins ("Watkins"), which the Examiner used to reject many of the claims.

Claim 7

In contrast to the Watkins catheter, Claim 7 of the present application recites, among other recitations, a cannula comprising "an elongate body having a proximal end, a distal end, a blood flow lumen extending therethrough from an inlet located adjacent to the proximal end, the inlet being open in the absence of positive pressure in the lumen" and "a plurality of discharge openings fluidly coupled with the blood flow lumen and located distal of the inlet."

Watkins does not disclose discharge openings located distal of the inlet, as is recited in Claim 7. Indeed, the distal openings 50b of the Watkins catheter include a valve means 53 *to prevent blood* from being discharged therefrom upon application of pressure to the catheter. Watkins, Col. 3, lines 48-59. Instead, Watkins discloses discharge openings positioned proximal of the inlet. Watkins does not disclose an inlet located adjacent to a proximal end of the lumen,

as is recited in Claim 7. Instead, as noted above, Watkins discloses a catheter in which the inlet is positioned at a distal end such that it can be advanced into the heart.

Moreover, Watkins does not disclose an inlet being open in absence of positive pressure in the lumen. Rather, Watkins discloses, with respect to the embodiment illustrated in Figure 5, an interior channel member 56 and a corresponding channel member 57 for measuring the pressure at openings in the Watkins catheter. The channel 57, for example, has a two-way valve between an open end portion 57a and a proximate end 57b of the channel for measuring pressures obtained in the aperture 57a. Watkins, Col. 4, lines 44-51. The aperture 57a may be capable of withdrawing blood from a patient's vasculature when pressure is applied to the channel. Watkins, however, does not disclose an "inlet being open in the absence of positive pressure in the lumen." Accordingly, for at least the reasons discussed above, Claim 7 is not anticipated by Watkins.

Claim 10

In contrast to the Watkins catheter, Claim 10 of the present application recites, among other limitations, an extracardiac pumping system comprising a main cannula portion comprising "a first blood flow lumen having a proximal end fluidly coupled to the pump, and a second blood flow lumen fluidly coupled with the pump and through which blood can be withdrawn from the vasculature through an inlet thereof" and "a plurality of discharge openings located distal of the inlet, the inlet being open when no blood is flowing."

As noted above with respect to Claim 7, Watkins does not disclose a discharge opening positioned distally of an inlet of the catheter. Rather, Watkins discloses an inlet at a distal end thereof and a discharge opening positioned proximally thereof. Furthermore, Watkins does not disclose an inlet being open when no blood is flowing. Instead, Watkins discloses a channel having an aperture that is generally closed and which is capable of withdrawing blood from a vasculature only when pressure is applied to the channel. Accordingly, Watkins fails to anticipate Claim 10. Thus, for release the reasons discussed above, Claim 10 is allowable over the cited art.

Claim 11

In contrast to the Watkins catheter, Claim 11 of the present application recites, among other limitations, an extracardiac pumping system comprising a percutaneous cannula with a main cannula portion comprising a blood flow lumen extending therethrough and an inlet configured to provide fluid flow into the blood flow lumen, and a tip portion extending from the main cannula portion to the distal end of the cannula and comprising a discharge opening "located distal of the inlet." As noted above with respect to Claims 7 and 10, Watkins fails to disclose a catheter having a discharge opening located distally of an inlet. Instead, Watkins discloses a heart assist catheter for direct application to a patient's heart in which the inlet, positioned at the distal-most end of the catheter, is positioned directly in the left ventricle of the patient's heart.

In sum, Watkins does teach each and every recitation of any of Claims 7, 10, and 11. Therefore, Claims 7, 10, and 11, and the dependent claims depending from those claims, are in condition for immediate allowance. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

New Claims

Applicant has added new Claims 110-114. These claims do not add new matter because they are supported by the application as originally filed. Applicant respectfully asserts that Claims 110-114 are in condition for immediate allowance for at least the reasons explained above.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee.

| Serial No. | Docket No. | Title | Filed |
|------------|-----------------|--|---------------|
| 10/078,283 | FORFLOW.008CP1 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | Feb. 14, 2002 |
| 11/417,652 | FORFLOW.8CP1DV1 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |
| 11/417,662 | FORFLOW.8CP1DV2 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |

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|------------|-----------------|--|---------------|
| 11/417,918 | FORFLOW.8CP1DV3 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |
| 11/418,377 | FORFLOW.8CP1DV4 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |
| 11/417,647 | FORFLOW.8CP1DV5 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |
| 11/417,937 | FORFLOW.8CP1DV6 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |
| 11/417,487 | FORFLOW.8CP1DV7 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |
| 11/418,489 | FORFLOW.8CP1DV8 | MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA | May 3, 3006 |
| 11/417,916 | ORQIS.007C1 | CANNULAE HAVING A REDIRECTING TIP | May 3, 3006 |
| 11/417,510 | ORQIS.007C2 | CANNULAE HAVING A REDIRECTING TIP | May 3, 3006 |
| 11/417,528 | ORQIS.007C3 | CANNULAE HAVING A REDIRECTING TIP | May 3, 3006 |
| 11/417,877 | ORQIS.007C4 | CANNULAE HAVING A REDIRECTING TIP | May 3, 3006 |
| 11/417,678 | ORQIS.007C5 | CANNULAE HAVING A REDIRECTING TIP | May 3, 3006 |
| 10/866,535 | ORQIS.021A | CANNULAE HAVING REDUCED FLOW RESISTANCE | June 10, 2004 |

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Application No.: 10/706,346
Filing Date: November 12, 2003

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: Nicholas M. Zovko
Nicholas M. Zovko
Registration No. 61,557
Attorney of Record
Customer No. 20,995
(951) 781-9231

APPENDIX